HFD-19

DEPARTMENT OF HEALTH & HUMAN SERVICES

m984N

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 10 1997

WARNING LETTER

Mr. Armand Kramedjian
President
The Hammer Corporation
4215 Wendell Drive, S.W.
Suite 203
Atlanta, Georgia 30336

Ref: 7-HFD-312-03

Dear Mr. Kramedjian:

This is in reference to "Maximum Strength Efedrin" marketed by your firm. The product is a bronchodilator and expectorant and contains 25 mg ephedrine hydrochloride and 100 mg guaifenesin per tablet.

The product is subject to final regulations covering bronchodilator and expectorant drug products found in Title 21 Code of Federal Regulations (21 CFR) part 341. Under those regulations, the acceptable dose of guaifenesin is 200 mg to 400 mg every four hours, not to exceed 2400 mg in 24 hours. The guaifenesin dose of 100 mg every four hours in "Maximum Strength Efedrin" does not meet the requirements cited above. We consider the product to be a "new drug" as described in section 201(p) of the Federal Food, Drug, and Cosmetic Act (the Act) which may not be legally marketed in the United States without an approved New Drug Application, as referenced under section 505(a) of the Act. The product is also misbranded under section 502 of the Act because the directions for use are inadequate for its intended purpose.

The above list of violations is not meant to be an all-inclusive list of deficiencies. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with the Act. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you take action immediately to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, which may include seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations. Your response should also include an explanation of each step being taken to prevent

recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. Your reply should be addressed to the Food and Drug Administration, Division of Labeling and Nonprescription Drug Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20857, Attention: Robert A. Eshelman, Compliance Officer.

Sincerely yours,

Bradford W. Williams
Director
Division of Labeling and Nonprescription
Drug Compliance
Office of Compliance
Center for Drug Evaluation and Research